IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LIMITED and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 2:10-cv-00128-RBS-FBS

TEVA PHARMACEUTICALS USA, INC.'S
ANSWER AND COUNTERCLAIM

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") hereby responds to Pfizer Inc.'s, Pfizer Limited's and Pfizer Ireland Pharmaceuticals' (collectively, "Pfizer") Complaint ("the Complaint") as follows:

Nature of the Action

1. No response is required from Teva USA to the extent that the allegations in Paragraph 1 of the Complaint are directed to Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), or to the extent that Paragraph 1 states conclusions of law. Teva USA admits that Pfizer asserts that this patent infringement action relates to Teva USA's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale and/or importation of 25 mg, 50 mg and 100 mg sildenafil citrate tablets. Teva USA denies the remaining allegations in Paragraph 1.

The Parties

2. Upon information and belief, Teva USA admits that Pfizer Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 of the Complaint and therefore denies the same.

4. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4 of the Complaint and therefore denies the same.

5. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same.

6. Teva USA admits that it is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. No response is required from Teva USA because the allegations in Paragraph 7 of the Complaint are directed solely to Teva Ltd.

8. No response is required from Teva USA to the extent that the allegations in Paragraph 8 of the Complaint are directed to Teva Ltd. Teva USA admits that it is an indirect wholly-owned subsidiary of Teva Ltd.

Jurisdiction and Venue

9. No response is required from Teva USA to the extent that the allegations in Paragraph 9 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations in Paragraph 9 of the Complaint are directed to Teva USA, Teva USA admits that Pfizer purports to bring this action under the Patent Laws of the United States. Teva USA further admits that Pfizer bases jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. No response is required from Teva USA to the extent that the allegations in Paragraph 10 of the Complaint are directed to Teva Ltd. To the extent that the allegations in Paragraph 10 are directed to Teva USA, Teva USA admits, for purposes of this action only, that venue with respect to Teva USA is proper in this judicial district under 28 U.S.C. § 1391.

11. Teva USA, for purposes of this action only, admits that this Court has personal jurisdiction over Teva USA. No response is required from Teva USA to the extent that Paragraph 11 of the Complaint states conclusions of law. Teva USA denies the remaining allegations in Paragraph 11 of the Complaint.

12. No response is required from Teva USA because the allegations in Paragraph 12 of the Complaint are directed solely to Teva Ltd.

Background

The ‘012 Patent

13. Teva USA admits that according to the face of U.S. Patent No. 6,469,012 (“the ‘012 patent”), the ‘012 patent is titled “Pyrazolopyrimidinones for the Treatment of Impotence,” and that it issued on October 22, 2002. Teva USA also admits that according to the face of the ‘012 patent, the ‘012 patent issued to Pfizer, Inc. as the assignee of Peter Ellis and Nicholas

Kenneth Terrett. Teva USA admits that the United States Patent and Trademark Office ("PTO") has reexamined the '012 patent, and that claims 1-23, 25 and 26 remain in the '012 patent. Teva USA admits that the PTO found that the subject matter described in claim 24 of the '012 patent is not patentable. Teva USA further admits that what appears to be a copy of the '012 patent is attached to the Complaint as Exhibit A.

14. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 14 of the Complaint and therefore denies the same.

15. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 15 of the Complaint and therefore denies the same.

Orange Book Listing for VIAGRA®

16. No response is required from Teva USA to the extent that the allegations in Paragraph 16 of the Complaint state conclusions of law. Teva USA admits that the FDA's Electronic Orange Book identifies "Pfizer Ireland" as the company that submitted New Drug Application No. 20-895 for Viagra®. Upon information and belief, Teva USA admits that Pfizer markets commercial formulations of sildenafil citrate under the trade name Viagra®. Teva USA also admits that the Electronic Orange Book identifies the '012 patent as purportedly covering Viagra®. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 16 of the Complaint and therefore denies the same.

17. Teva USA admits that the FDA's Electronic Orange Book identifies the expiration date of the '012 patent as October 22, 2019.

18. Teva USA admits that the FDA's Electronic Orange Book identifies U.S. Patent No. 5,250,534 ("the '534 patent") as purportedly covering Viagra®, and identifies the expiration date of the '534 patent as March 27, 2012.

Teva's ANDA

19. Teva USA admits that Teva USA sent a letter to Pfizer Inc. and Pfizer Ireland on or about December 17, 2004, notifying Pfizer Inc. and Pfizer Ireland that Teva USA had submitted ANDA No. 77-342 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale and/or importation of Teva's ANDA products.

20. Teva USA admits that Teva USA's December 17, 2004 letter stated the factual and legal bases for Teva USA's opinion that the '012 patent is invalid, unenforceable and not infringed by the manufacture, use, or sale of Teva's ANDA products.

21. No response is required from Teva USA to the extent that the allegations in Paragraph 21 of the Complaint are directed to Teva Ltd. Teva USA admits that it caused ANDA No. 77-342 to be submitted to the FDA. Teva USA denies the remaining allegations in Paragraph 21 of the Complaint.

22. Teva admits that the FDA granted tentative approval for ANDA No. 77-342 on April, 24, 2007.

23. No response is required from Teva USA to the extent that the allegations in Paragraph 23 of the Complaint are directed to Teva Ltd. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 23 of the Complaint and therefore denies same.

COUNT I
(Patent Infringement)

24. Teva USA repeats and incorporates herein by reference its responses to Paragraphs 1-23 of the Complaint.

25. No response is required from Teva USA to the extent that the allegations in Paragraph 25 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 25 states conclusions of law. To the extent that the allegations in Paragraph 25 are directed to Teva USA, Teva USA denies the same.

26. No response is required from Teva USA to the extent that the allegations in Paragraph 26 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 26 states conclusions of law. Teva USA admits that it was aware of the '012 patent at the time it submitted ANDA No. 77-342 to the FDA.

27. No response is required from Teva USA to the extent that the allegations in Paragraph 27 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 27 states conclusions of law. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegation in Paragraph 27 of the Complaint that Teva USA intends to engage in the manufacture, use, offer for sale, sale, and/or importation of its ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012, and therefore denies the same. Teva USA denies the remaining allegations in Paragraph 27 of the Complaint.

28. No response is required from Teva USA to the extent that the allegations in Paragraph 28 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 28 states conclusions of law. To the extent that the allegations in Paragraph 28 are directed to Teva USA, Teva USA denies the same.

29. No response is required from Teva USA to the extent that the allegations in Paragraph 29 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 29 states

conclusions of law. To the extent that the allegations in Paragraph 29 are directed to Teva USA, Teva USA denies the same.

30. No response is required from Teva USA to the extent that the allegations in Paragraph 30 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 30 states conclusions of law. To the extent that the allegations in Paragraph 30 are directed to Teva USA, Teva USA denies the same.

31. No response is required from Teva USA to the extent that the allegations in Paragraph 31 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 31 states conclusions of law. To the extent that the allegations in Paragraph 31 are directed to Teva USA, Teva USA denies the same.

32. No response is required from Teva USA to the extent that the allegations in Paragraph 32 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 32 states conclusions of law. To the extent that the allegations in Paragraph 32 are directed to Teva USA, Teva USA denies the same.

COUNT II
(Declaratory Judgment of Infringement)

33. Teva USA repeats and incorporates herein by reference its responses to Paragraphs 1-32 of the Complaint.

34. No response is required from Teva USA to the extent that the allegations in Paragraph 34 of the Complaint are directed to Teva Ltd. Teva USA admits that Pfizer asserts its Count II under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Teva USA admits that there is an actual controversy between Pfizer and Teva USA.

35. No response is required from Teva USA to the extent that the allegations in Paragraph 35 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 35 states

conclusions of law or background information rather than allegations. Teva USA denies the remaining allegations in Paragraph 35 of the Complaint.

36. No response is required from Teva USA to the extent that the allegations in Paragraph 36 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 36 states conclusions of law. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegation in Paragraph 36 of the Complaint that Teva USA intends to engage in the manufacture, use, offer for sale, sale, and/or importation of its ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012, and therefore denies same. Teva USA denies the remaining allegations in Paragraph 36 of the Complaint.

37. No response is required from Teva USA to the extent that the allegations in Paragraph 37 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 37 states conclusions of law. To the extent that the allegations in Paragraph 37 are directed to Teva USA, Teva USA denies the same.

38. No response is required from Teva USA to the extent that the allegations in Paragraph 38 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 38 states conclusions of law. To the extent that the allegations in Paragraph 38 are directed to Teva USA, Teva USA denies the same.

39. No response is required from Teva USA to the extent that the allegations in Paragraph 39 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 39 states conclusions of law. To the extent that the allegations in Paragraph 39 are directed to Teva USA, Teva USA denies the same.

40. No response is required from Teva USA to the extent that the allegations in Paragraph 40 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 40 states conclusions of law. To the extent that the allegations in Paragraph 40 are directed to Teva USA, Teva USA denies the same.

41. No response is required from Teva USA to the extent that the allegations in Paragraph 41 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 41 states conclusions of law. To the extent that the allegations in Paragraph 41 are directed to Teva USA, Teva USA denies the same.

42. Teva USA further answers that any allegations in the Complaint requiring a response from Teva USA that are not specifically admitted are denied, and that no response is required from Teva USA to the extent that the allegations in the Complaint are directed to Teva Ltd. Teva USA also denies that Pfizer is entitled to the judgment and relief prayed for in Paragraphs A through G of the Complaint.

TEVA USA'S AFFIRMATIVE DEFENSES

First Affirmative Defense

43. The Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense

44. The manufacture, use, offer for sale, sale or importation of the sildenafil citrate products specified in ANDA No. 77-342 does not and will not infringe any valid and enforceable claim of the '012 patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense

45. The claims of the '012 patent are invalid under 35 U.S.C. §§ 101 *et seq.*, including §§ 102, 103 and 112.

46. Teva USA specifically reserves the right to assert each and every other defense that may become evident in the course of discovery, including, but not limited to, inequitable conduct.

COUNTERCLAIM FOR DECLARATORY JUDGMENT

Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA") for its counterclaim against Counterclaim-Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer"), alleges as follows:

Nature of the Action

1. Teva USA incorporates by reference Paragraphs 1-46 set forth above.

2. This is an action for a judgment declaring that the claims of the '012 patent are invalid, and that Teva USA has not infringed and will not infringe any claim of the '012 patent, either directly, or by inducing or contributing to infringement by others, by engaging in the commercial manufacture, use, sale and/or importation of Teva's ANDA products. The '012 patent is attached as Exhibit A to Pfizer's Complaint.

The Parties

3. Counterclaim-Plaintiff Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Counterclaim-Defendant Pfizer Inc. has averred that it is a corporation organized under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York.

5. Counterclaim-Defendant Pfizer Limited has averred that it is a corporation organized under the laws of England, with its principal place of business at Ramsgate Road, Sandwich, Kent, England.

6. Counterclaim-Defendant Pfizer Ireland Pharmaceuticals has averred that it is a partnership existing pursuant to the laws of Ireland, with its registered office at Pottery Road,

Dun Laoghaire, County Dublin, Republic of Ireland.

Jurisdiction and Venue

7. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court has subject matter jurisdiction over this counterclaim pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a) and 2202.

9. The Counterclaim-Defendants have submitted to the personal jurisdiction of this Court by filing their Complaint in this action.

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b)-(d).

The Existence of an Actual Controversy

11. As a consequence of the allegations of patent infringement made by Counterclaim-Defendants against Teva USA in their Complaint, an actual controversy exists between Teva USA and Counterclaim-Defendants regarding the validity and infringement of the '012 patent.

12. Counterclaim-Defendant Pfizer Inc. has averred that it is an assignee of the '012 patent. Counterclaim-Defendant Pfizer Limited has averred that it is the owner of a beneficial interest in the '012 patent. Counterclaim-Defendant Pfizer Ireland Pharmaceuticals has averred that it is an exclusive licensee under the '012 patent. Counterclaim-Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals have averred that they have all right, title and interest in the '012 patent and the right to sue for infringement thereof. The '012 patent is titled "Pyrazolopyrimidinones for the Treatment of Impotence" and states on its face that it issued on October 22, 2002.

Non-infringement and Invalidity

13. Teva USA has not infringed, contributed to the infringement of, or induced the infringement of, and has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the '012 patent. The commercial manufacture, use, sale, offer for sale and/or importation of the Teva ANDA products identified in ANDA No. 77-342 by Teva USA after obtaining approval from the FDA for those products, would not directly infringe, contribute to the infringement of or induce the infringement of any valid claim of the '012 patent.

14. Each of the claims of the '012 patent is invalid for failure to comply with the Patent Laws of the United States, including the conditions and requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.,* including §§ 102, 103 and 112.

PRAYER FOR RELIEF

WHEREFORE, Teva USA requests that the Court enter Judgment in its favor and against Plaintiffs and Counterclaim-Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals as follows:

A. Dismissing all claims against Teva USA in Pfizer's Complaint with prejudice;

B. Declaring that Teva USA has not infringed, contributed to the infringement of, or induced the infringement of, and will not infringe, contribute to the infringement of, or induce the infringement of any of the claims of the '012 patent by engaging in the commercial manufacture, use, sale, offer for sale and/or importation of Teva's ANDA products identified in ANDA No. 77-342;

C. Declaring invalid each of the claims of the '012 patent;

D. Adjudging that Plaintiffs and Counterclaim-Defendants are not entitled to any

declaratory or injunctive relief or any alleged damages for alleged patent infringement by Teva USA;

E. Adjudging this to be an exceptional case under 35 U.S.C. § 285, and awarding to Teva USA its reasonable attorney fees, costs and expenses; and

F. Granting to Teva USA such other and further relief as this Court may deem just, proper or equitable.

Dated: April 29, 2010

Respectfully submitted,

___/s/_____

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CERTIFICATE OF SERVICE

I hereby certify that on April 29 2010, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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